

### ***Remarks***

Claims 32, 36 and 37 are pending. The remaining claims have been canceled to expedite allowance of the instant application.

Applicant acknowledges and appreciates the Telephonic Interview that took place on April 15, 2009, with the Examiner and Supervisory Patent Examiner Larry Helms, during which the rejection of the claims under 35 USC 101 and Applicant's response of December 29, 2008 were discussed. Applicant also appreciates the follow-up conversation between the Examiner and the undersigned that took place on April 22, 2009, and during which submission of remarks after final rejection to move the application to allowance was discussed. Applicant accordingly submits the following amendments and remarks in view of these communications.

### **Rejection under 35 U.S.C. § 101**

Claims 32, 36 and 37 stand finally rejected based on the contention that the claimed invention lacks utility. Applicant responds as follows.

As discussed during the aforementioned Interview, Applicant agrees with the Examiner in that, in order to satisfy the requirements of 35 U.S.C. § 101, an invention must be found to have patentable utility at the time the application was filed, but for at least the following reasons, disagrees that the instant application lacks such utility. In this regard, Applicant hereby reiterates the remarks presented in Applicant's response filed December 29, 2009, and emphasizes that MPEP § 2107.02 specifies that it is imperative that Office personnel use specificity in setting forth a rejection under 35 U.S.C. 101 and support any factual conclusions because, by using specificity, the applicant will be able to identify the assumptions made by the Office in setting forth the rejection and will be able to address those assumptions properly. This section of the MPEP also specifies that a *prima facie* showing of a lack of specific or substantial utility **must** establish that it is more likely than not that a person of ordinary skill in the art would not consider any utility asserted by the applicant to be specific and substantial (Applicant's emphasis).

In imposing the instant rejection, Applicant respectfully submits that the Office Action does not adequately take into account Applicant's previous response, which Applicant submits

establishes that it is more likely than not that a person of ordinary skill in the art *would* consider a utility asserted by the Applicant to be specific and substantial. In particular, Applicant submits that the declaration of Dr. Leo I. Gordon submitted with the response dated December 29, 2009, establishes that one skilled in the art would consider a utility asserted by the Applicant to be specific and substantial from the specification as filed. In this regard, Dr. Gordon's declaration sets forth his opinion that the MCT-1 protein to which the presently claimed antibodies are directed had properties that would have made this protein likely to be involved in cell cycle regulation pathways that were known at the time to be involved in malignancies. Specifically, in addition to structural homology between the MCT-1 protein and cyclins, as well as the observation that MCT-1 overexpression decreases duration of the G1/S phase of the cell cycle, Dr. Gordon points out that the application discloses that MCT-1 has transforming ability in vitro (see page 2 of Dr. Gordon's declaration, third bullet point). Dr. Gordon also expresses his opinion that these data strongly suggested that MCT-1 was involved in unregulated cell proliferation of the type common to many malignancies, and that in view of this, a utility for antibodies specific for the MCT-1 protein was evident to him. Thus, Applicant respectfully submits it is established on the record that one skilled in the art would recognize a specific and substantial utility for antibodies to the MCT-1 protein. Applicant nevertheless further points out that, irrespective of the degree of homology between MCT-1 and cyclin proteins, the instant application as filed discloses that, when MCT-1 protein was overexpressed in fibroblasts, the overexpression of MCT-1 increased the proliferative rate of the cells by decreasing the length of the G1 phase without causing a reciprocal increase in the durations of the S or G2-M phases. (See page 39, lines 12-15). Further, when the transforming ability of MCT-1 was assessed by soft agar growth, it was demonstrated that MCT-1-overexpressing cells remained viable and continued to proliferate, in contrast to the negative control. (See page 39, beginning on line 19, through page 40, line 2.) Therefore, the application as filed presents data indicating that the MCT-1 protein is involved in cell cycle regulation and moreover has transforming ability. Applicant respectfully submits it is self-evident from at least these properties of the MCT-1 protein that antibodies to the protein have patentable utility.

Thus, in view of the aforementioned communications between the undersigned and the Examiner, and the remarks presented herein, it is respectfully submitted that the rejection has been overcome. The Examiner is accordingly requested to reconsider and withdraw the rejection.

***Conclusion***

Based on the arguments and amendments presented herein, Applicant believes all the pending claims are now in condition for allowance and respectfully requests the Examiner to allow all the claims. Any fees due for submission of this paper may be charged to deposit account number 08-2442.

Respectfully submitted,  
HODGSON RUSS LLP

/John D. Lopinski/

By \_\_\_\_\_  
John D. Lopinski, Ph.D.  
Reg. No. 50,846

The Guaranty Building  
140 Pearl Street, Suite 100  
Buffalo, NY 14202-4040  
Tel:(716) 848-1430  
DATE: May 28, 2009